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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,736	10/11/2006	Michael V. Agrez	65350US(54086)	9415
21874 7590 04/01/2009 EDWARDS ANGELL PALMER & DODGE LLP P.O. BOX 55874 BOSTON, MA 02205				
EXAMINER				
DUFFY, BRADLEY				
ART UNIT		PAPER NUMBER		
1643				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/575,736

**Applicant(s)**

AGREZ, MICHAEL V.

**Examiner**

BRADLEY DUFFY

**Art Unit**

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 86-107 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 88-91, 94-97, 99, 101, 103 and 107 is/are objected to.
- 8) ☒ Claim(s) 1, 86, 87, 92, 93, 98, 100, 102 and 104-106 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-849)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. The preliminary amendment filed February 20, 2009 is acknowledged. Claims 2-85 have been canceled. Claims 86-107 have been newly added.
2. Notably, claims 88-91, 94-97, 99, 101, 103 and 107 depend from canceled claims. For this reason, these claims have *not* been included in any restriction group because the subject matter of these claims cannot be determined.
3. Claims 1 and 86-107 are pending in the application. Claims 1 and 86-87, 92-93, 98, 102 and 104-106 are currently subject to restriction.

### ***Election/Restrictions***

4. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I. Claim 92, insofar as the claim is drawn to a method for prophylaxis, i.e., prevention, of a cancer in a mammal, wherein cancer cells of the cancer express a MAP kinase and the method comprises treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:4.

Group II. Claim 92, insofar as the claim is drawn to a method for prophylaxis, i.e., prevention, of a cancer in a mammal, wherein cancer cells of the cancer express a MAP kinase and the method comprises treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:5.

Group III. Claim 92, insofar as the claim is drawn to a method for prophylaxis,

i.e., prevention, of a cancer in a mammal, wherein cancer cells of the cancer express a MAP kinase and the method comprises treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:6.

Group IV. Claim 92, insofar as the claim is drawn to a method for prophylaxis, i.e., prevention, of a cancer in a mammal, wherein cancer cells of the cancer express a MAP kinase and the method comprises treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:7.

Group V. Claim 92, insofar as the claim is drawn to a method for prophylaxis, i.e., prevention, of a cancer in a mammal, wherein cancer cells of the cancer express a MAP kinase and the method comprises treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:8.

Group VI. Claim 92, insofar as the claim is drawn to a method for prophylaxis, i.e., prevention, of a cancer in a mammal, wherein cancer cells of the cancer express a MAP kinase and the method comprises treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:9.

Group VII. Claim 92, insofar as the claim is drawn to a method for prophylaxis, i.e., prevention, of a cancer in a mammal, wherein cancer cells of the cancer express a MAP kinase and the method comprises treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:10.

Group VIII. Claim 92, insofar as the claim is drawn to a method for prophylaxis, i.e., prevention, of a cancer in a mammal, wherein cancer cells of the cancer express a MAP kinase and the method comprises treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:11.

Group IX. Claim 92, insofar as the claim is drawn to a method for treatment of

a cancer in a mammal, wherein cancer cells of the cancer express a MAP kinase and the method comprises treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:4.

Group X. Claim 92, insofar as the claim is drawn to a method for treatment of a cancer in a mammal, wherein cancer cells of the cancer express a MAP kinase and the method comprises treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:5.

Group XI. Claim 92, insofar as the claim is drawn to a method for treatment of a cancer in a mammal, wherein cancer cells of the cancer express a MAP kinase and the method comprises treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:6.

Group XII. Claim 92, insofar as the claim is drawn to a method for treatment of a cancer in a mammal, wherein cancer cells of the cancer express a MAP kinase and the method comprises treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:7.

Group XIII. Claim 92, insofar as the claim is drawn to a method for treatment of a cancer in a mammal, wherein cancer cells of the cancer express a MAP kinase and the method comprises treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:8.

Group XIV. Claim 92, insofar as the claim is drawn to a method for treatment of a cancer in a mammal, wherein cancer cells of the cancer express a MAP kinase and the method comprises treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:9.

Group XV. Claim 92, insofar as the claim is drawn to a method for treatment of

a cancer in a mammal, wherein cancer cells of the cancer express a MAP kinase and the method comprises treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:10.

Group XVI. Claim 92, insofar as the claim is drawn to a method for treatment of a cancer in a mammal, wherein cancer cells of the cancer express a MAP kinase and the method comprises treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:11.

5. Claims 1, 86-87, 93, 98, 102, and 104-106 are linking claims, linking the inventions of Groups I-VIII, or strictly in the alternative Groups IX-XVIII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

6. The inventions listed as Groups I- XVIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

To have a general inventive concept under PCT Rule 13.1, the inventions need to be linked by a special technical feature. In this case, each of the inventions of Groups I- XVIII do not appear to be linked by a common concept, or special technical

feature. Nevertheless, since the actual technical feature that is particular to the invention of claim 1 is treating a mammal that has cancer expressing a MAP kinase with an effective amount of a polypeptide that binds to a binding domain of the MAP kinase for a cytoplasmic binding domain of a  $\beta$  integrin subunit for the MAP kinase, it is aptly noted that Agrez (W) 2001/000677 A1), IDS filed 4/13/06) teach methods of treating a mammal that has cancer expressing a MAP kinase with an effective amount of a polypeptide that binds to a binding domain of the MAP kinase for a cytoplasmic binding domain of a  $\beta$  integrin subunit for the MAP kinase (see entire document, e.g., pages 24 and 55). Accordingly, since Agrez et al teach the technical feature of the invention of claim 1, it is not a special technical feature and the groups do not relate to a single general inventive concept as required under PCT Rule 13.1. Furthermore, PCT Rules 13.1 and 13.2 do not provide for a single general inventive concept to comprise more than the first mentioned product, the first mentioned method for making said product, and the first mentioned method for using said product.

For these reasons, the special technical feature of the invention of Group I is preventing cancer in a mammal without cancer, wherein cancer cells of the cancer express a MAP kinase by treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:4.

The special technical feature of the invention of Group II is preventing cancer in a mammal without cancer, wherein cancer cells of the cancer express a MAP kinase by treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:5.

The special technical feature of the invention of Group III is preventing cancer in a mammal without cancer, wherein cancer cells of the cancer express a MAP kinase by treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:6.

The special technical feature of the invention of Group IV is preventing cancer in a mammal without cancer, wherein cancer cells of the cancer express a MAP kinase by treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:7.

The special technical feature of the invention of Group V is preventing cancer in a mammal without cancer, wherein cancer cells of the cancer express a MAP kinase by treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:8.

The special technical feature of the invention of Group VI is preventing cancer in a mammal without cancer, wherein cancer cells of the cancer express a MAP kinase by treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:9.

The special technical feature of the invention of Group VII is preventing cancer in a mammal without cancer, wherein cancer cells of the cancer express a MAP kinase by treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:10.

The special technical feature of the invention of Group VIII is preventing cancer in a mammal without cancer, wherein cancer cells of the cancer express a MAP kinase by treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:11.

The special technical feature of the invention of Group IX is treating cancer in a mammal with cancer, wherein cancer cells of the cancer express a MAP kinase by treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:4.



The special technical feature of the invention of Group X is treating cancer in a mammal with cancer, wherein cancer cells of the cancer express a MAP kinase by treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:5.

The special technical feature of the invention of Group XI is treating cancer in a mammal with cancer, wherein cancer cells of the cancer express a MAP kinase by treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:6.

The special technical feature of the invention of Group XII is treating cancer in a mammal with cancer, wherein cancer cells of the cancer express a MAP kinase by treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:7.

The special technical feature of the invention of Group XIII is treating cancer in a mammal with cancer, wherein cancer cells of the cancer express a MAP kinase by treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:8.

The special technical feature of the invention of Group XIV is treating cancer in a mammal with cancer, wherein cancer cells of the cancer express a MAP kinase by treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:9.

The special technical feature of the invention of Group XV is treating cancer in a mammal with cancer, wherein cancer cells of the cancer express a MAP kinase by treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:10.

The special technical feature of the invention of Group XVI is treating cancer in a mammal with cancer, wherein cancer cells of the cancer express a MAP kinase by treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:11.

**7. Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined and, if necessary, a species of invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.** The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

**8.** Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

***Conclusion***

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached at Monday through Friday from 7:00 AM to 4:30 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,  
Brad Duffy  
571-272-9935

/Stephen L. Rawlings/  
Primary Examiner, Art Unit 1643

/bd/  
Examiner, Art Unit 1643  
March 18, 2009